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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/301,842	04/29/1999	BRIAN C.A. FERNANDES	P-8383.00	6147

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EXAMINER	
LAM, ANN Y	
ART UNIT	PAPER NUMBER
3763	

DATE MAILED: 11/30/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/301,842	FERNANDES ET AL.	
	Examiner	Art Unit	
	Ann Y. Lam	3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 May 2001* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☒ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. Claim 26 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 26 recites the limitation "the metal or metal alloy" in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 1-4, 9, 10, 12, 14-20 and 73-74 are rejected under 35 U.S.C. 102(b) as being anticipated by Helmus et al., 5,447,724.

Helmus discloses an implantable medical device, see column 9, lines 52-68, comprising a body portion overlaid by a fabric overlayer, see column 9, lines 38-48, the body portion comprising at least one polymer, intimately mixed with at least one

therapeutic agent, see column 9, line 46, wherein the therapeutic agent is capable of being released from the body portion of the device, see column 3, lines 34-47, and column 6, lines 18-25.

As to claim 2, the constituent material comprises at least a polymer, see column 9, line 46.

As to claims 3 and 4, the constituent material comprises a polymer, specifically silicon, see column 2, lines 39-47.

As to claims 9 and 10, the therapeutic agent comprises an anti-inflammatory agent, specifically cortisone, see column 2, line 6.

As to claim 12, the therapeutic agent further comprises an antimicrobial agent, see column 2, line 7.

As to claim 14, the therapeutic agent is coated onto the body portion of the device, see column 4, lines 12-24.

As to claim 15, the therapeutic agent is compounded into the body portion of the device, see column 4, lines 12-24 and column 9, lines 28-49.

As to claim 16, the body portion of the device comprises a liquid core comprising the therapeutic agent, see column 4, lines 12-24 and column 9, lines 38-48.

As to claim 17, the therapeutic agent comprises an antimicrobial agent, see column 2, line 7.

As to claims 18 and 19, the medical device is a prosthetic heart valve, see column 2, lines 66-67.

As to claim 20, the fabric overlayer takes the form of a sheath, pouch, an encasement, an enclosure, a layer, a film, or a coating, see column 4, lines 12-24, and column 9, lines 28-49.

As to claims 73-74, an artificial pump is disclosed, see column 9, lines 60-68.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

3. Claims 5-8, 21, 22, 24-26, 28-30, 32, 34-39, 41, 42, 44-50, 52, 53, 55-57, 59-67 and 69-72 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., 5,447,724, in view of Tweden et al., 5,895,419.

Helmus discloses the invention substantially as claimed, see above. Additionally, Helmus discloses that other devices that may be used in the invention include artificial heart components, vascular grafts, heart valves, cardiovascular sutures, etc., see column 9, lines 58-62.

However, Helmus does not disclose the fabric overlayer comprising a knitted or woven fabric of polymer fibers, nor does Helmus disclose the polymer comprising polyethyleneteraphthalate. Helmus also does not disclose the heart valve prosthesis as comprising a sewing ring, nor an annuloplasty ring.

Tweden discloses a suture/sewing cuff or fabric comprising a knitted or woven fabric of polyester, see column 2, lines 45-50, and see column 3, lines 30-33. Tweden also discloses that for stented bioprosthetic heart valves, the fabric used for the sewing cuff could be coated with a therapeutic agent, see column 2, lines 51-67. It would have been obvious to one of ordinary skill in the art to use the Helmus teachings to provide the therapeutic agent in the knitted or woven fabric polymer fibers on the Tweden heart valve, as a type of medical device specifically disclosed by Helmus that may be coated with a therapeutic agent according to the Helmus invention.

Specifically with respect to claim 8, Tweden discloses that the polymer fibers comprise polyethyleneteraphthalate, see column 5, lines 34-35.

As to claim 21, Tweden discloses a sewing ring (66).

As to claims 22, 30, the polymer insert comprises silicone, see column 3, line 36-38.

As to claims 24, 28, 35, 36, Tweden discloses that the heart valve may be bioprosthetic or mechanical, see column 2, lines 3-6, and lines 30-35.

As to claims 26, 37, 38, 48, 49, 64, 65, the body portion comprises a metal, specifically titanium, see column 3, line 40.

As to claims 29, 60, Tweden discloses that the heart valve comprises a polymer insert containing struts attached to tissue leaflets to form a valve housing, wherein a fabric sheath encloses the polymer insert to form sewing ring, see column 2, line 31.

As to claims 41, 56, Tweden discloses an annuloplasty ring (22).

As to claims 71 and 72, the sewing ring constitutes an annular insert.

4. Claims 11 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., 5,447,724, in view of Fearnot et al., 5,609,629.

Helmus discloses the invention substantially as claimed, see above. More specifically, Helmus discloses that the therapeutic agent comprises an anti-inflammatory agent, see column 2, line 6. Helmus also discloses that devices that could be coated with the therapeutic agents include vascular stents, see column 9, line 63. However, Helmus does not disclose the anti-inflammatory agent as being dexamethasone.

Fearnot teaches that a layer of dexamethasone coated on an implantable medical device for implantation into, for example, the vascular system, see column 4, line 33. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to apply a layer of dexamethasone onto an implantable medical device for the vascular system, as taught by Fearnot, using the methods taught by Helmus.

5. Claims 23, 27, 33, 40, 43, 51, 54, 58 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., 5,447,724, in view of Tweden et al., 5,895,419, and further in view of Fearnot et al., 5,609,629.

Helmus-in-view-of-Tweden disclose the invention substantially as claimed, see above. More specifically, Helmus discloses that the therapeutic agent comprises an anti-inflammatory agent, see column 2, line 6. Helmus also discloses that devices that could be coated with the therapeutic agents include vascular stents, see column 9, line 63. However, Helmus does not disclose the anti-inflammatory agent as being dexamethasone.

Fearnot teaches that a layer of dexamethasone coated on an implantable medical device for implantation into, for example, the vascular system, see column 4, line 33. Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made, to apply a layer of dexamethasone, as taught by Fearnot, onto implantable medical devices as taught by Helmus-in-view-of-Tweden.

6. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., 5,447,724, in view of Chanda et al., 5,645,587.

Helmus discloses the invention substantially as claimed, see above. Additionally, Helmus discloses that the therapeutic agents may include anticalcifying drugs to prevent calcification of biomedical materials such as used in heart valves or artificial heart, see column 6, line 68 – column 7, line 3. However, Helmus does not disclose the agent being gentamicin or rifampicin.

Chanda teaches that heparin after neutralization with gentamicin is essential in prevention of calcification in tissue grafts, which is the main cause of failure of bioprosthetic heart valves, see column 3, lines 45-47, and lines 61-62. It would have been obvious to one of ordinary skill in the art at the time the invention was made to provide a gentamicin in combination with heparin on the Helmus heart valve in order to prevent calcification.

7. Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Helmus et al., 5,447,724, in view of Tweden et al., 5,895,419, as applied to claim 30 above, and further in view of Myers, 5,716,397.

Helmus-in-view-of-Tweden disclose the invention substantially as claimed, see above. Also, Tweden discloses an annuloplasty ring (22). However, Helmus-in-view-of-Tweden does not disclose a polymer insert comprising radiopaque flexible silicone rubber.

Myers discloses an annuloplasty ring consisting of a soft core of silicone rubber impregnated with radiopaque salt. It would have been obvious to one of ordinary skill in the art to provide radiopaque silicone rubber in the Helmus-in-view-of-Tweden polymer insert, as a known material used in forming an annuloplasty ring.

Response to Arguments

Applicant's arguments with respect to the above claims have been considered but are moot in view of the new ground(s) of rejection. Helmus discloses a polymer intimately mixed with a therapeutic agent, as described above.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Batich et al., 5,607,417, and Cima et al., 5,869,170, both disclose medical devices coated with a polymer and therapeutic agent.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Y. Lam whose telephone number is (703) 306-5560. The examiner can normally be reached on T-F 8-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Richard Seidel can be reached on (703)308-5115. The fax phone numbers for the organization where this application or proceeding is assigned are (703)305-3590 for regular communications and (703)306-4520 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0858.

A.L.
November 17, 2001

ANHTUAN T. NGUYEN
PRIMARY EXAMINER
11/17/01